the ground that "it is not clear from the specification to what characteristics of an animal this phrase refers, nor is it clear how one would judge such a characteristic."

It is respectfully submitted that the term carcass quality is well-known to those of ordinary skill in the art. The Examiner's attention is kindly invited to US Patent No. 6,248,939 B1 which issued to Leto et al. on June 19, 2001 (a copy of which is hereby included for the Examiner's convenience). This reference accompanied the previously submitted Information Disclosure Statements.

Attention is kindly invited to column 4 at lines 25-60 it is stated that to "have utility in animal feed ration as a means of improving carcass quality and subsequently improving the human diet, high oleic corn must be capably of supplying enough oleic acid in the diet to raise the oleic acid level in the meat. . . ." In other words, carcass quality refers to the composition (proportions of lean, fat and bone) of the meat. Attention in further invited to Example 3 which starts in column 16 at line 13. It is stated in column 16 at lines 17-20 that by "replacing some or all of the supplemental animal fat in a feed ratio with the oil present in high oil, high oleic corn, it will be possible to produce meat products having less saturated fats. . . ." Evaluation of carcass quality is described in column 17 at lines 33-36: the "effect of the treatments on carcass quality can be evaluated by measuring average carcass weight, average back fat, average percent lean yield, and average actual yield. . . ."

Accordingly, it is respectfully submitted that the term "carcass quality" is quite clear to one of ordinary skill in the art.

With respect to the term "carcass quality improving amount", it is respectfully submitted that this term is quite clear to one of ordinary skill in the art as demonstrated by the above quote from the '939 patent, column 4 at lines 25-60, wherein it is stated that to "have utility in animal feed ration as a means of improving carcass quality and subsequently improving the human diet, high oleic corn must be capably of supplying enough oleic acid in the diet to raise the oleic acid level in the meat. . . ." Thus, one skilled in the art would be able to determine the appropriate amount without engaging in undue experimentation. It is respectfully submitted that the metes and bounds of the claim are clear.

With respect to the language "feeding the animal", this is intended to be an active process step.

The term "reverse complement" is what the Examiner refers to as a complement on page 4 of the Office Action. It is described in the specification on page 16 at lines 29-34 with respect to "antisense RNA".

The term "shrunken 1 intron/exon" is described on page 16 at lines 3-7 at "a region of the shrunken 1 gene from corn. The **particular intron/exon used in the present** invention is derived from a non-coding region ("exon 1/intron 1") of the shrunken 1 gene **and is identical to the sequence in GenBank accession #C02382 from nucleotides 1138 through 2220**. . . ."

(Emphasis added.) It is respectfully submitted that it is quite clear what region is referred to by the claim.

The term "functionally equivalent subfragment" is referring to the nucleic acid fragment encoding a corn delta-9 stearoyl ACP desaturase.

The term "isolated nucleic acid fragment comprising a corn oleosin promoter" is referring to the promoter whether it is full length or partial.

Claims 172-174, sections (ii) and (iv), claim 175(b) and claim 176 have been rejected as being indefinite over the language "corn oleosin promoter hybridizes to the." It is respectfully submitted that when these sections are read, as a whole, it is clear that it is the isolated nucleic acid fragment (comprising the promoter sequence) which hybridizes.

Regarding claims 172 and 173, section (ii), (iii) and (iv), claim 175 and 176, it is respectfully submitted that these claims are clear with respect to what is operably linked to suitable regulatory sequences. It is stated on page 16 of the specification, starting at line 36 through line 3 of page 17 that the term "operably linked" "refers to the association of nucleic acid sequences on a single nucleic acid fragment so that the function of one is affected by the other. For example, a promoter is operably linked with a coding sequence when it is capable of affecting the expression of that coding sequence, i.e., that the coding sequence is under the transcriptional control of the promoter. Coding sequences can be operably linked to regulatory sequences in sense or antisense orientation."

Regarding claim 175, the phrase "the corn grain" does not appear in line 2 of this claim. It simply says ". . .animal feed derived from the processing of corn grain. . . ." However, the article "a" has been inserted before corn grain to address this perceived problem. Claim 175 has also been amended to recite that the oil is comprised of not less than 60% oleic acid of the total oil content of the seed.

Claims 172-176 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is alleged on pages 5-6 of the Office that the "claims are broadly drawn in that they encompass methods for improving the carcass quality of any animal, and they do not specifically indicate the amount of feed necessary to effect the goal of improving carcass quality. Further, as discussed above, neither the claims nor the specification offer guidance as to who to measure carcass quality or what aspect of carcass quality would be improved by the consumption of the animal feed derived from the plants described in the claims. . ."

Carcass quality refers to the factors that influence the processing capabilities of both the lean and fat tissues, as well as the consumer acceptability and palatability of both fresh and processed meat products (AMSA (1971) "Meat Evaluation Handbook" American Meat Science Association Savoy, IL). Quality can be quantified using a series of laboratory

measures to evaluate weight, purge (amount of free liquid in retail packaging), appearance, water holding capacity, light reflectance, color, pH, moisture, fat, protein, cooking loss, instrumental tenderness; as well as sensory characteristics such as juiciness, tenderness, chewiness, meat flavor, off flavor and shelf life (Prusa and Fedler (1996) Proceedings: Roche Animal Nutrition and Health Veterinary Education Seminar; Meat and Livestock Commission (1996) "Blueprint for Quality British Pork", Meat Technology Transfer Group, Milton Keynes, UK). Carcass quality can also be defined in terms of the quantity and quality of specific carcass components, physical and morphological attributes, biochemical properties, microbiological and hygienic state and human nutritive properties. For example, Wood (Wood et al. (1984) "Fat in Animal Nutrition" pp 407 (Wiseman Ed) Butterworths, London) describes the important influence of the quantity and quality of carcass fat on firmness, appearance and flavor of meat from cattle, sheep and pigs; while Moran (Moran (1996*) Anim Feed Sci Tech 58*:91-99) describes opportunities to alter specific meat attributes to enhance the human health aspects of meat.

In addition the Examiner's attention is kindly invited US 6,248,939 B1 which is discussed above. Example 3 which is set forth in columns 16 and 17 discusses the use of high oil, high oleic corn in animal feed ration as a means of improving quality meat. It is stated in column 17 at lines 34-36 that the "effect of the treatments on carcass quality can be evaluated by measuring average carcass weight, average back fat, average percent lean yield and average actual yield." Thus, one of ordinary skill in the art would know how to measure/assess carcass quality. Such knowledge existed prior to the filing date of the instant application. Determination of the amount of feed can readily be assessed by one skilled in the art without engaging in undue experimentation.

The law is well settled that the specification need not teach or disclose in detail that which is well known in the art. Genentech, Inc. v. Novo Nordisk A/S, 42 USPQ2d1001, , 1005 (Fed. Cir.1997); In re Meyers, 162 USPQ 668 (CCPA 1969).

The references cited on page 6 of the Office Action seem to be inapposite in that they concern replacing maize with barley. The instant invention concerns replacing standard maize with corn grain obtained from a corn plant or plant part comprising any of the chimeric genes recited in the claims. Thus, the present invention concerns altering oil profile in corn using chimeric genes comprising nucleic acid fragments described in the application and suitable regulatory sequences to create transgenic corn plants having altered lipid profiles and this altered corn can then be used as an animal feed ration to improve carcass quality.

Applicant respectfully submits that in view of the above discussion and reference, undue experimentation would not be required to practice the claimed invention.

It is alleged on page 8 of the Office Action that the "specification teaches plants in which sense and anti-sense nucleic acids encoding corn delta-9 stearoyl ACP desaturase are introduced into plants, and in both instances the resulting plant displayed high saturate fatty

acid composition. The mechanism by which this occurs is unclear, and therefore, it is not possible to predict the effect that adding other nucleic acids to the plants would have on the plant. . . . Due to the lack of guidance in the specification, the high level of unpredictability with regard to which nucleic acids would be useful for producing such plants, undue experimentation would be required to produce animal feed from plants as broadly claimed."

The law is well settled that it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. See, Newman v. Quigg, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

The Examiner's attention is kindly invited to Example 8 in the specification which describes (1) transgenic corn with high saturate fatty acid composition in the grain, (2) transgenic corn with a high oleic acid content in the grain and (3) transgenic corn with high levels of saturated and oleic acid in kernels. The specification and examples show one of ordinary skill in the art how the practice the claimed invention.

Claims 172-176 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, has possession of the claimed invention.

The term "functionally equivalent subfragment" is described in the specification on page 13 at lines 29-37 and page 14 discusses the % identity language. Thus, contrary to the allegation on page 10 of the Office, it is respectfully submitted that there is written description in the specification for the foregoing language.

In addition, the examples clearly demonstrate conception of the invention. There is no magical relationship between the number of representative examples and the breadth of the claims. The number and variety of examples are irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated." In re Borkowski, 164 USPQ 642 (CCPA 1970).

It is contended on page 10 of the Office Action that ". . . the mechanism by which the introduced nucleic acids act in plants is unkown, and therefore 'the function' of the nucleic acids in the plants is unknown." As was indicated above, and is reiterated here, the law is well settled that it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. See, Newman v. Quigg, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

Accordingly, in view of the above discussion, withdrawal of the rejection of the claims under 35 USC §112, first and second paragraphs, is respectfully requested.

A petition for a three (3) month extension of time accompanies this response along with the Version with Markings To Show Changes Made and copies of any references noted in the response.

It is respectfully submitted that the claims are now in form for allowance which allowance is respectfully requested.

Please charge any fees associated with the filing of this response to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company). If the fee is insufficient or incorrect, please charge or credit the balance to the above-identified deposit account.

Respectfully submitted,

Lynne M. Christenbury

LYNNE M. CHRISTENBURY
ATTORNEY FOR APPLICANT
REGISTRATION NO. 30,971
TELEPHONE: 302-992-5481
FACSIMILE: 302-892-1026

Dated: November 5, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In showing the changes, deleted material is shown Bracketed, and inserted material is shown as underlined.

In the Abstract

Kindly delete the Title and Abstract appearing on page 61 in their entirety and replace it with the following:

--TITLE

A METHOD FOR IMPROVING THE CARCASS QUALITY OF AN ANIMAL

ABSTRACT

A method for improving the carcass quality of an animal is described. This method involves the preparation and use of nucleic acid fragments comprising all or substantially all of a corn oleosin promoter, a stearoyl-ACP desaturase and a delta-12 desaturase which can be used individually or in combination to modify the lipid profile of corn are described. Chimeric genes incorporating such nucleic acid fragments and suitable regulatory sequences can be used to create transgenic corn plants having altered lipid profiles are also described. --.

In the Specification

Page 1, lines 1 and 2, delete "TITLE GENES FOR DESATURASES TO ALTER LIPID PROFILES IN CORN" and replace it with the following:

--TITLE

A METHOD FOR IMPROVING THE CARCASS QUALITY OF AN ANIMAL--.

Page 14, lines 9-36 has been amended as follows:

--Moreover, the skilled artisan recognizes that substantially similar nucleic acid sequences encompassed by this invention are also defined by their ability to hybridize, under moderately stringent conditions (for example, 0.5 X SSC, 0.1% SDS, 60° C) with the sequences exemplified herein, or to any portion of the nucleotide sequences reported herein and which are functionally equivalent to the promoter of the invention. Preferred substantially similar nucleic acid sequences encompassed by this invention are those sequences that are 80% identical to the nucleic acid fragments reported herein or which are 80% identical to any portion of the nucleotide sequences reported herein. More preferred are nucleic acid fragments which are 90% identical to the nucleic acid sequences reported herein, or which are 90% identical to any portion of the nucleotide sequences reported herein. Most preferred are nucleic acid fragments which are 95% identical to the nucleic acid sequences

reported herein, or which are 95% identical to any portion of the nucleotide sequences reported herein. Sequence alignments and percent similarity calculations may be determined using the Megalign program of the LASARGENE bioinformatics computing suite (DNASTAR Inc., Madison, WI). Multiple alignment of the sequences are performed using the Clustal method of alignment (Higgins and Sharp (1989) *CABIOS. 5*:151-153) with the default parameters (GAP PENALTY=10, GAP LENGTH PENALTY=10). Default parameters for pairwise alignments and calculation of percent identiy of protein sequences using the Clustal method are KTUPLE=1, GAP PENALTY=3, WINDOW=5 and DIAGONALS SAVED=5. For nucleic acids these parameters are GAP PENALTY=10, GAP LENGTH PENALTY=10, KTUPLE=2, GAP PENALTY=5, WINDOW=4 and DIAGONALS SAVED=4. A "substantial portion" of an amino acid or nucleotide sequence comprises enough of the amino acid sequence of a polypeptide or the nucleotide sequence of a gene to afford putative identification of that polypeptide or gene, either by manual evaluation of the sequence by one skilled in the art, or by computer-automated sequence comparison and identification using algorithms such as BLAST (Altschul, S. F., et al., (1993) *J. Mol. Biol. 215*:403-410) and Gapped Blast (Altschul, S. F. et al., (1997) *Nucleic Acids Res. 25*:3389-3402)[; see also www.ncbi.nlm.nih.gov/BLAST/)].

In the Claims

175. (once amended) A method of improving the carcass quality of an animal by feeding the animal a carcass quality improving amount of animal feed derived from the processing of a corn grain obtained from a corn plant or plant part which comprises a chimeric gene comprising (a) an isolated nucleic acid fragment encoding a corn delta-12 desaturase wherein said fragment has a nucleic acid sequence identity of at least 80% based on the Clustal method of alignment when compared to a nucleic acid as set forth in SEQ ID NOS: 1, 58 or 59, or a functionally equivalent subfragment thereof, or the reverse complement of either the fragment or subfragment, (b) an isolated nucleic acid fragment comprising a corn oleosin promoter wherein said promoter can be full length or partial and said promoter: (1) comprises a nucleotide sequence having a sequence identity of at least 80% based on the Clustal method of alignment when compared to the nucleotide sequence in any of SEQ ID NOS:19 or 38-49 or (2) the isolated nucleic acid fragment comprising a full length or partial corn oleosin promoter hybridizes to the nucleotide sequence set forth in SEQ ID NOS: 19 or 38-49 under moderately stringent conditions, operably linked to suitable regulatory sequences, and (c) a shrunken 1 intron/exon, operably linked to suitable regulatory sequences;

wherein expresssion of the chimeric gene results in an altered corn oleic acid phenotype, and

further wherein the corn grain has an oil content in the range from about 6% to about 10% on a dry matter basis and further wherein said oil is comprised of not less than [about] 60% oleic acid of the total oil content of the seed.